

DEA Trends & Update

Honolulu, HI Pharmacy Diversion Awareness Conference

January 22-23, 2017



The United States Department of Justice

Drug Enforcement Administration

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Associate Section Chief
Pharmaceutical Investigations
Section
Diversion Control Division





Goals and Objectives

- Public Health Epidemic
- Impact on Society
- Criminal Activity
- The Controlled Substances Act: Checks & Balances
- Drugs of Abuse
- Legal obligations: DEA registrant
- The DEA Response
- Disposal

Public Health Epidemic





“Primum non nocere”



On an average Day in the U.S.:



- § More than **650,000 opioid prescriptions** dispensed₁
- § **3,900 people** initiate nonmedical use of prescription opioids₂
- § **580 people** initiate heroin use₂

1. **Source:** IMS Health National Prescription Audit₁
2. SAMHSA National Survey on Drug Use and Health₂
3. CDC National Vital Statistics System₃



Public Health Epidemic

2000-2015

Over **550,000** unintentional drug overdose deaths in the US

2015

52,404 drug-related overdose deaths

143 deaths every 24 hours (**129** in '14)

1 death every 10.07 minutes (**11.16** minutes '14)

33,091 deaths involved opioids, including heroin (**91**)

***17,536** deaths involved opioid pain relievers (**48**)

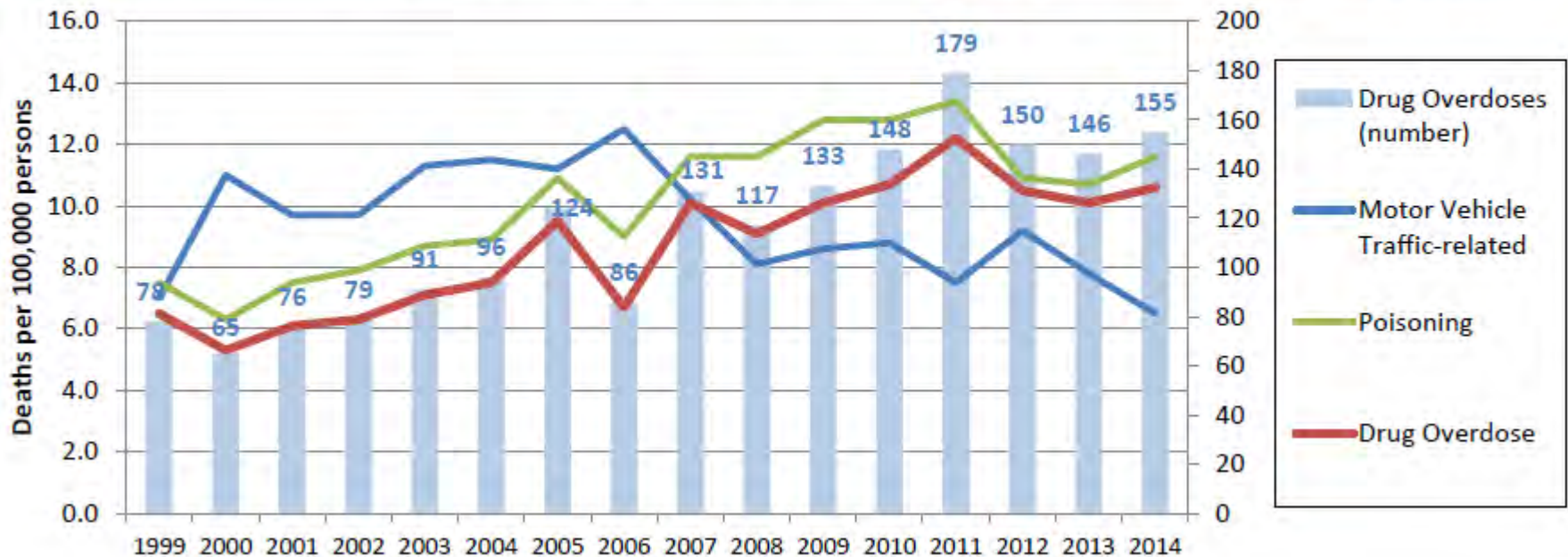
*Opioid Pain relievers (other than synthetic opioids) ICD-10 codes (T40.2, T40.3, & T40.6) excluding the category predominated by illicit fentanyl

CDC National Center for Health Statistics/Morbidity and Mortality Weekly Report (MMWR); December 30, 2016



2014 Comparison

Figure 1. Drug overdose death rates* compared to motor vehicle-related death rates, Hawaii residents, 1999-2014
(Lines show age-adjusted death rates (per 100,000 residents), while actual number of fatalities is indicated by bar and label.)



Source: HAWAII DEPARTMENT OF HEALTH <http://health.hawaii.gov/injuryprevention/>
Released October, 2015



Opioid Pain Relievers contributed to 35% of Drug Overdose Deaths

Table 1. Drug overdose deaths: Demographic characteristics, Hawaii residents, 2010-2014

		Average annual number	Percent	Average annual rate per 100,000 residents
Gender	Female	51	33%	8.6
	Male	104	67%	16.6
Age (in years)*	15-24	8	5%	4.1
	25-44	53	33%	14.0
	45-54	48	32%	25.8
	55 and older	47	31%	12.1
County of residence	Hawaii	20	14%	12.0
	Honolulu	105	65%	12.2
	Kauai	5	3%	-
	Maui	26	18%	17.5

This document was produced in conjunction with CDC's Core Violence and Injury Prevention Program under Cooperative Agreement 11-1101.

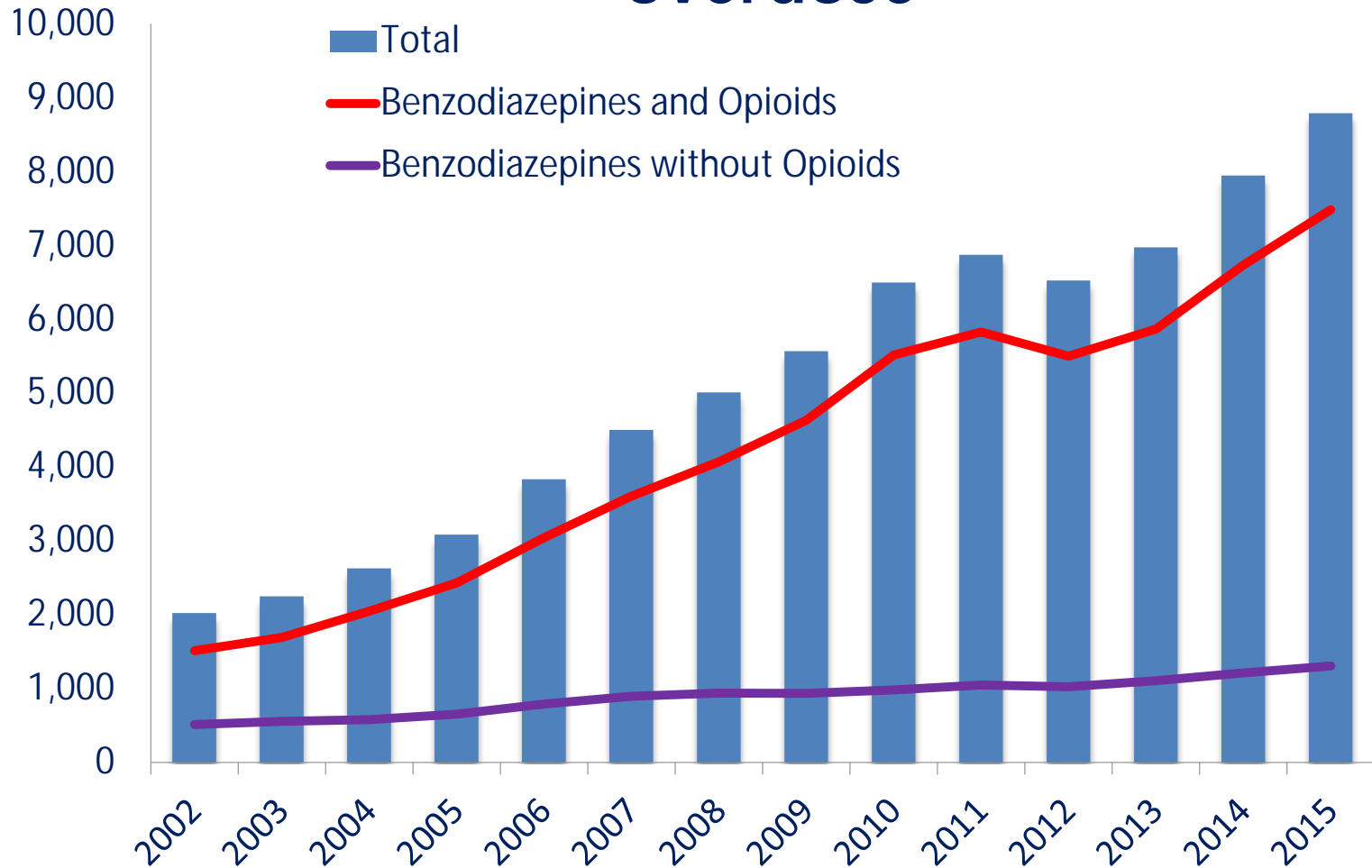
Source: HAWAII DEPARTMENT OF HEALTH <http://health.hawaii.gov/injuryprevention/>

Released October, 2015

§ Between 2006 -2014: Hawaii's overdose rate has increased 83%--- double the national average of 37% during that time period



Opioid involvement in benzodiazepine overdose

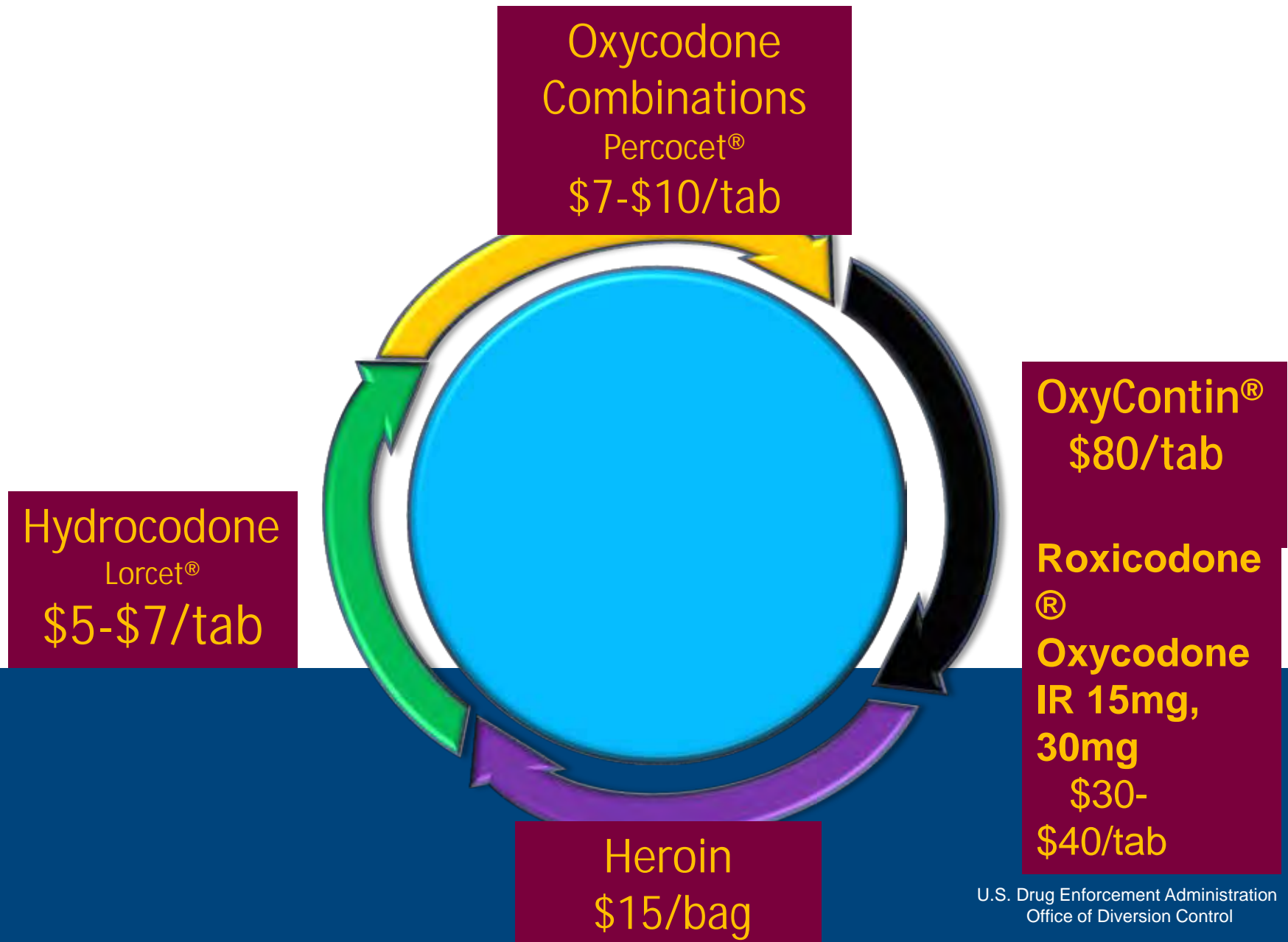




Prescription Opiates v. Heroin



Circle of Addiction & the Next Generation



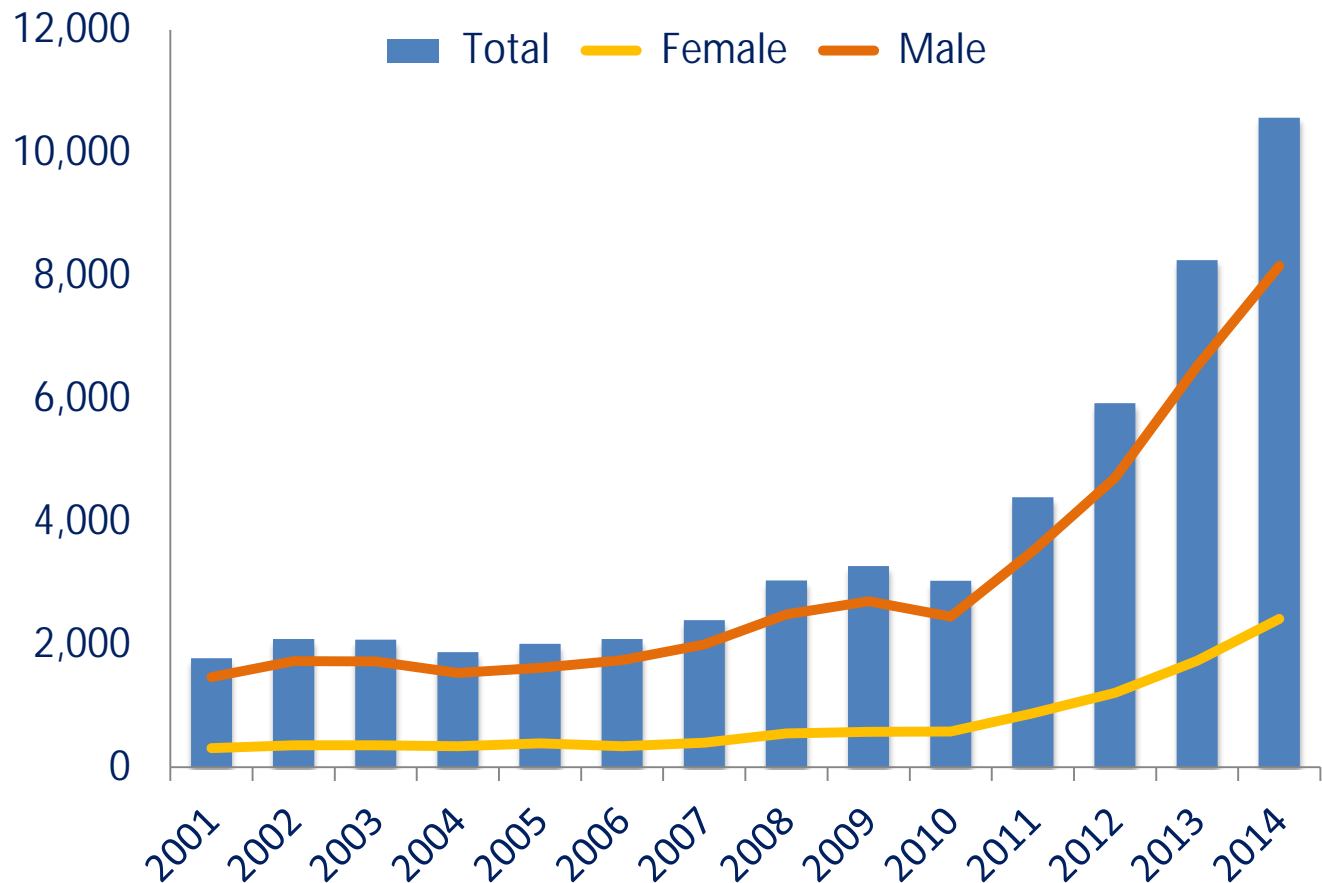


Scope of the Problem

CDC (2016):

Heroin deaths
more than triple
between 2010-2014

“This increase . . .
has been shown to
be closely tied to
opioid pain reliever
misuse and
dependence.”

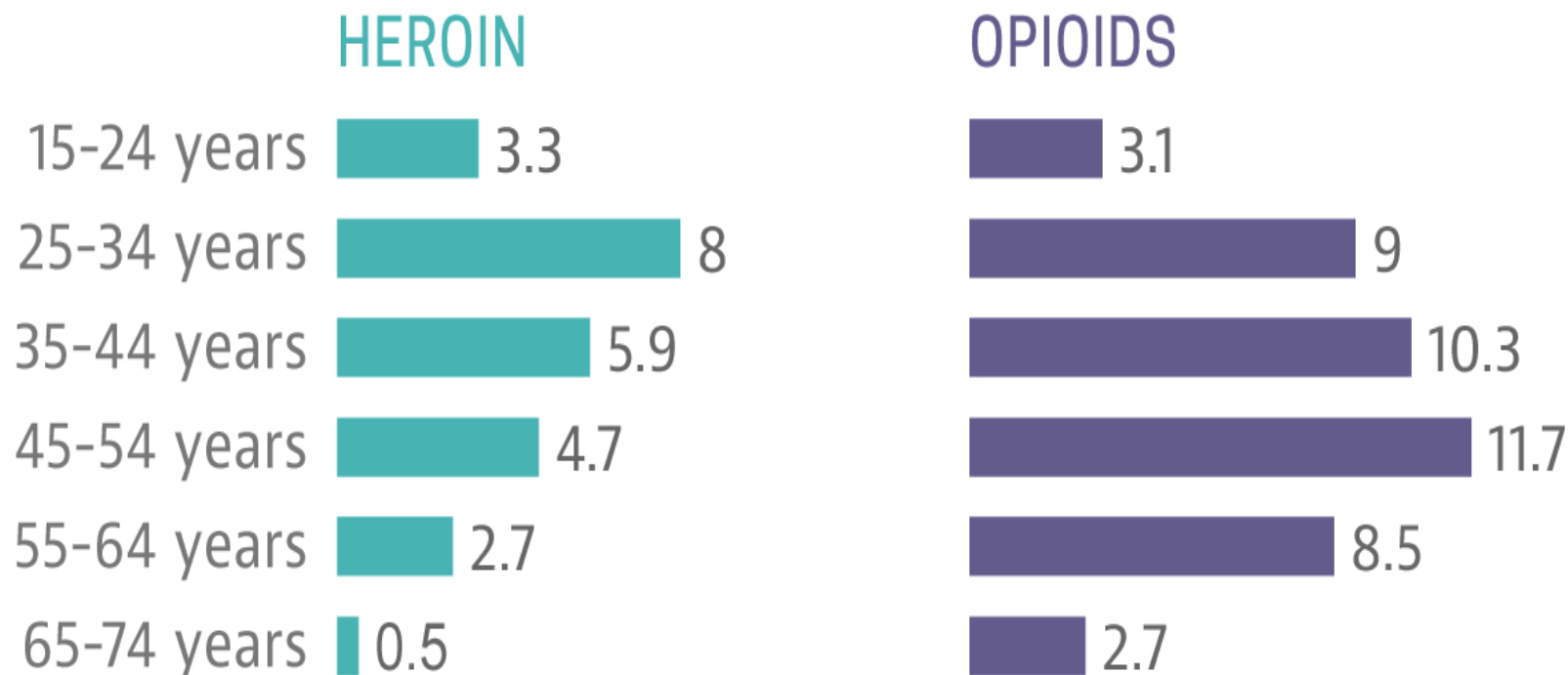


Source: National Center for Health Statistics, CDC Wonder



Overdoses in 2014

Overdose Deaths by Age in 2014 per 100,000 people



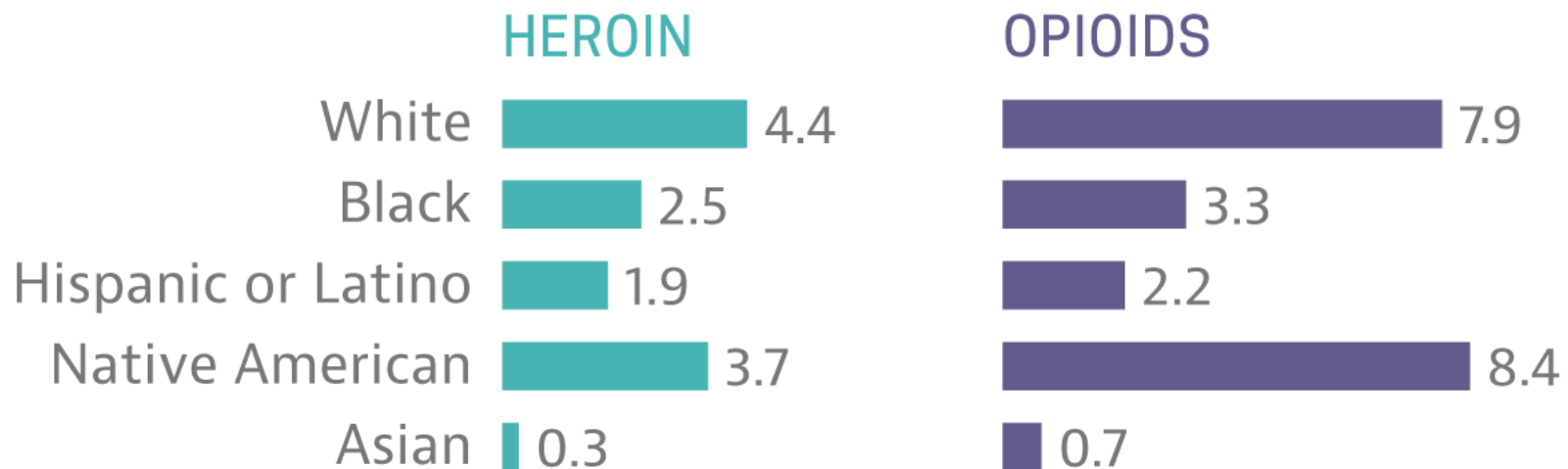
Source: CDC

Data: CDC



Everyone is Impacted

Overdose Deaths by Race in 2014 per 100,000 people



Data: CDC

Source: CDC

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The Examiner

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'Liaisons Dangereuses'

New approach to classic P. 19



Playoff possibilities

Schedule favors Skins P. 35

Cooling down



60° 34°

DETAILS P. 4

POLITICS

Stalemate on 'cliff'

Sides stop talking;
Obama's rate hikes
may be flexible. P. 13

LOCAL

FBI analyst busted

Heroin use spikes in area suburbs

Pill addicts risk deadly drug



Community Impact?

Heroin trafficking organizations relocating to areas where prescription drug abuse is on the rise

Heroin traffickers pave the way for increasing crime and violence

Law enforcement and prosecutors eventually fighting the problem on two fronts (prescription opiate diversion and heroin distribution) further depleting resources

Communities suffer

Violence





Violence Related to Controlled Substance Pharmaceuticals

NEW YORK POST Page Six
TUESDAY, JUNE 21, 2011 / Telerec. 55 / Weather: P. 15
METRO EDITION www.nypost.com \$1.00

ASSASSIN



1 Rushing for maximum, the assassin streaks through the door.
2 Gun in his right hand, he walks coolly through an aisle.
3 He pulls his cap over his face as he leaves the store.
4 Now a mass murderer, he walks out into the sunlight.

Chilling anatomy of drugstore massacre

He never gave them a chance. The cold-blooded killer who massacred four people in a Long Island pharmacy methodically shot each victim, shocking, step-by-step surveillance footage of the slaughter revealed yesterday.

PAGES 4-5

NEW YORK POST Page Six
THURSDAY, JUNE 23, 2011 / Telerec. 55 / Weather: P. 15
METRO EDITION www.nypost.com \$1.00

DRUGSTORE MASSACRE

Husband and wife busted in Rx-slay horror



PAIN KILLER

David Laffler is the man caught on video wearing a fake beard (top) who slaughtered four people in a pharmacy to fund his wife Melissa's addiction, cops said yesterday.

PAGES 4-5



The 1960s/70s/80s



Uppers - Amphetamines



Quaalude



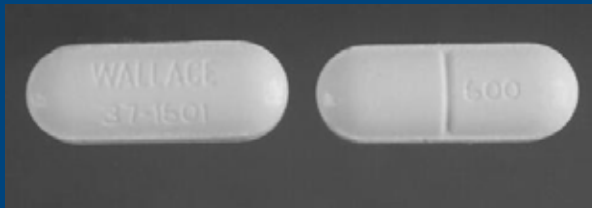
"Ts and Blues"



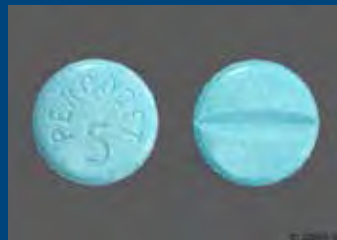
Downers - Barbiturates



Hydromorphone



Meprobamate



Oxycodone/APAP



21 "Fours and Doors"

Rx Drug Ads on TV –

Educational or Influential ?

Overweight? Suffering from anxiety or erectile dysfunction? Well, relief is just a prescription pill away according to the endless television ads promoting prescription drugs.





10 mg



20 mg



40 mg



80 mg



160 mg



The 1990s

OxyContin® Tablets
(oxycodone hydrochloride controlled-release)



jackie jones

Bluelight Crew



Join Date: Jul 2008

Location: A spoonful of sugar
helps the medicine go down.

Posts: 5,589

20-02-2014 15:32

#19



ZohydroER
(hydrocodone bitartrate)
EXTENDED-RELEASE CAPSULES

1st

Oral, Extended Release
Hydrocodone without
Acetaminophen for Treating
Chronic Pain

PDUFA Date March 1, 2013



REPLY

QUOTE



Bigfanofthemdrugs

Moderator

Drug Culture
Cannabis Discussion



Join Date: Mar 2012

Location: The Limbic System

20-02-2014 20:20

#20



Idk what you guys are tripping about, I'm stoked to get in on some of that, hydrocodone is one of my favorite opioids. It's just as euphoric as oxy IMO.



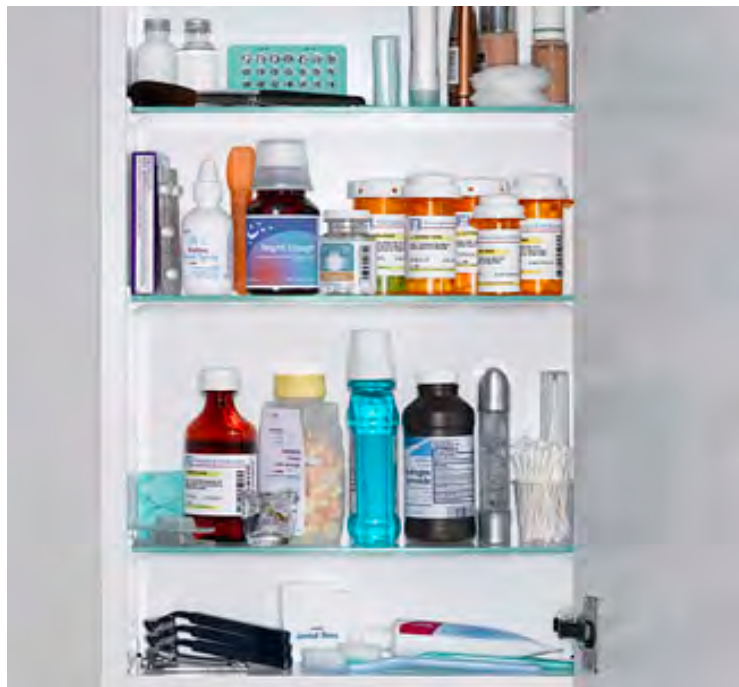
**Prescription Drug Abuse
is driven by**

**Indiscriminate Prescribing
Criminal Activity**



Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!



Patients Often Prescribed Extra Painkillers, Many Share Them

Two new U.S. studies shed light on opioid epidemic

John Hopkins Study:

- +60% had leftover opioids they hung on for “future use”
- 20% shared their medications
- 8% likely will share w/ friend
- 14% likely will share w/ relative
- 10% securely lock their medication

https://www.nlm.nih.gov/medlineplus/news/fullstory_159336.html

University of Pennsylvania Dental School Study:

More than half of the narcotics prescribed for wisdom teeth removal go unused...findings suggest that more than **100** million pills prescribed go unused...leaving the door open for possible misuse or abuse.

Source: <https://www.pennmedicine.org/news/news-releases/2016/september/100-million-prescription-opioid>

Survey of Long-Term Painkiller Users

- Majority say their doctor talked about possibility of addiction or dependence – **61%** say there was no discussion about plan to get them off.
- Majority say they use the drugs to relieve pain. Other major reasons for taking them:
 - 20% - "for fun or get high"
 - 14% - "to deal with day-to-day stress"
 - 10% - "to relax or relieve tension"
- Other Findings:
 - 34% admit being dependent or addicted
 - 17% have taken painkillers that were not specifically prescribed for them
 - 14% have given their painkillers to a family member or friend
 - 20% know or suspect someone was using, taking or selling their painkillers

Our Youth

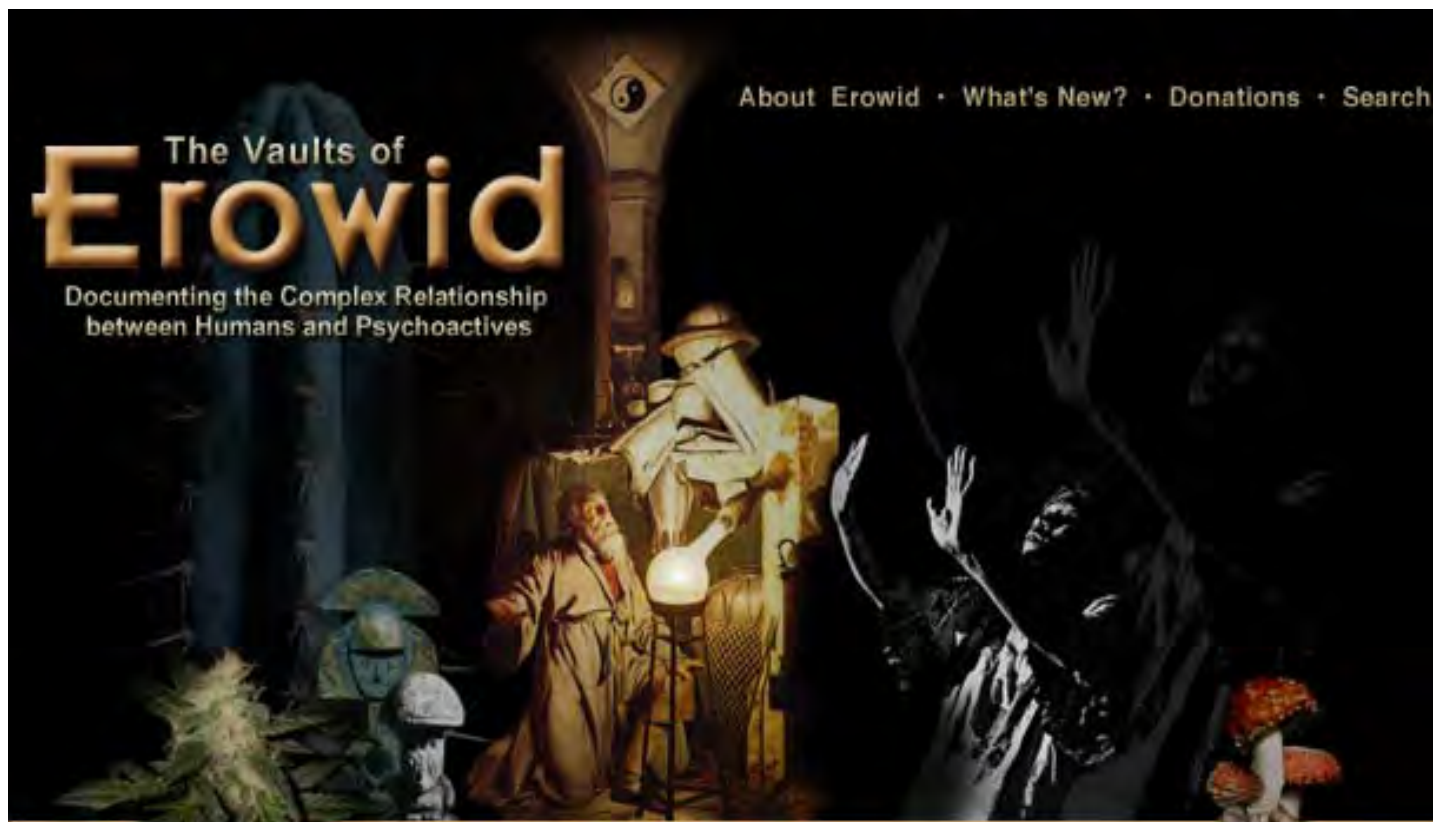


U.S. Drug Enforcement Administration
Office of Diversion Control



Where else do our kids get their information from?

www.erowid.org




Where do kids get their information from?

www.bluelight.org

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Drug Discussion	North America & South America
Drug Studies	North & South American
Drugs in the Media	Social & Drug Discussion
Basic Drug Discussion	North & South American
Advanced Drug	Events

THE FRONT PAGE 

A Letter to Bluelight and MAPS Forum members From Brad Burge (MAPS) and Sebastians_Ghost (BL)

by Sebastians_ghost Published on 05-04-2013 06:57





It is with great pride and enthusiasm that we announce today a major collaboration between Bluelight.ru and the Multidisciplinary Association for Psychedelic Studies.

Through the efforts of Brad Burge, MAPS' Director of Communications, Rick Doblin, MAPS' Founder and Executive Director, Sebastians_Ghost and The_Love_Bandit of Bluelight.ru, we will soon undertake an exciting partnership to reinvigorate the MAPS forum and increase opportunities for public education about psychedelic science and medicine. The existing plaintext email MAPS Forum will be migrating to Bluelight.ru, the world's leading drug information website. We're aiming to unveil the new MAPS Forums on Bluelight shortly before the Psychedelic Science 2013 symposium in mid-April.

In the coming weeks, the MAPS Forum will no longer be linked from maps.org. Instead, MAPS will provide a link to the new MAPS Forum hosted at Bluelight. MAPS will work closely with Bluelight to encourage public participation in our new "home" at Bluelight.ru as the migration of the MAPS Forum topics is completed.

...

start  Bluelight - The Front ... 

Criminal Activity





Egregious Activity (Not on the fringes)



United States V. Alvin Yee, M.D.

Dr. Yee primarily met with his “patients” in Starbucks cafes throughout Orange County, California.

He would see up to a dozen patients each night between 7:00 and 11:00 p.m. and wrote these “patients” prescriptions, primarily for opiates, in exchange for cash.

Yee pled guilty to distributing millions of dollars in oxycodone, oxymorphone, hydrocodone, hydromorphone, Adderall® and alprazolam outside the course of professional practice and without a legitimate medical purpose.





United States V. Alvin Yee, M.D.

CURES Data (PMP)

During a one-year time period, Yee wrote prescriptions for a total of 876,222 dosage units of all medications combined.

52% of all prescriptions (458,056 dosage units) written by Yee were for oxycodone (92%-30mg) during the one-year period.

96% - oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone.

Almost half of Yee's patients were 25 and under.



The Controlled Substances Act: Checks & Balances





Mission

The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

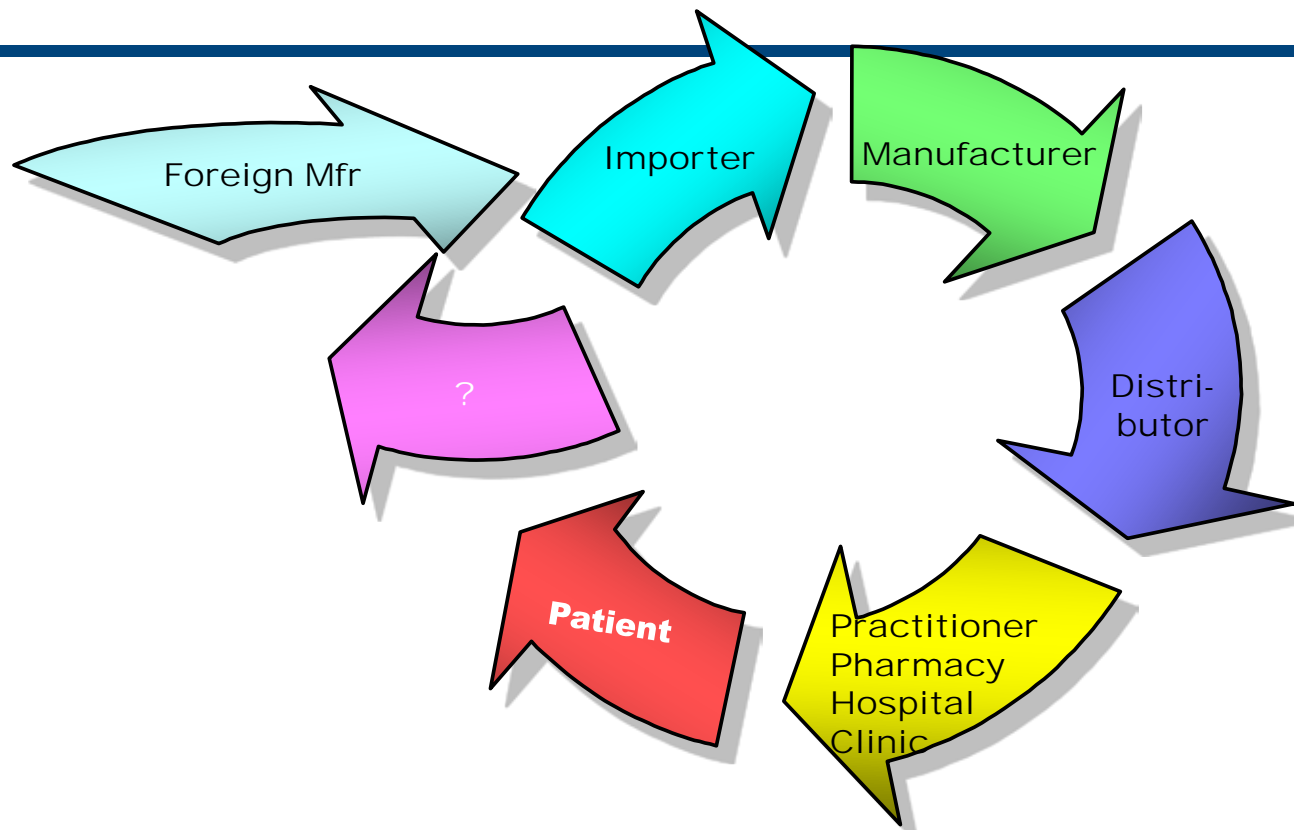
while ...

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs.





Closed System of Distribution

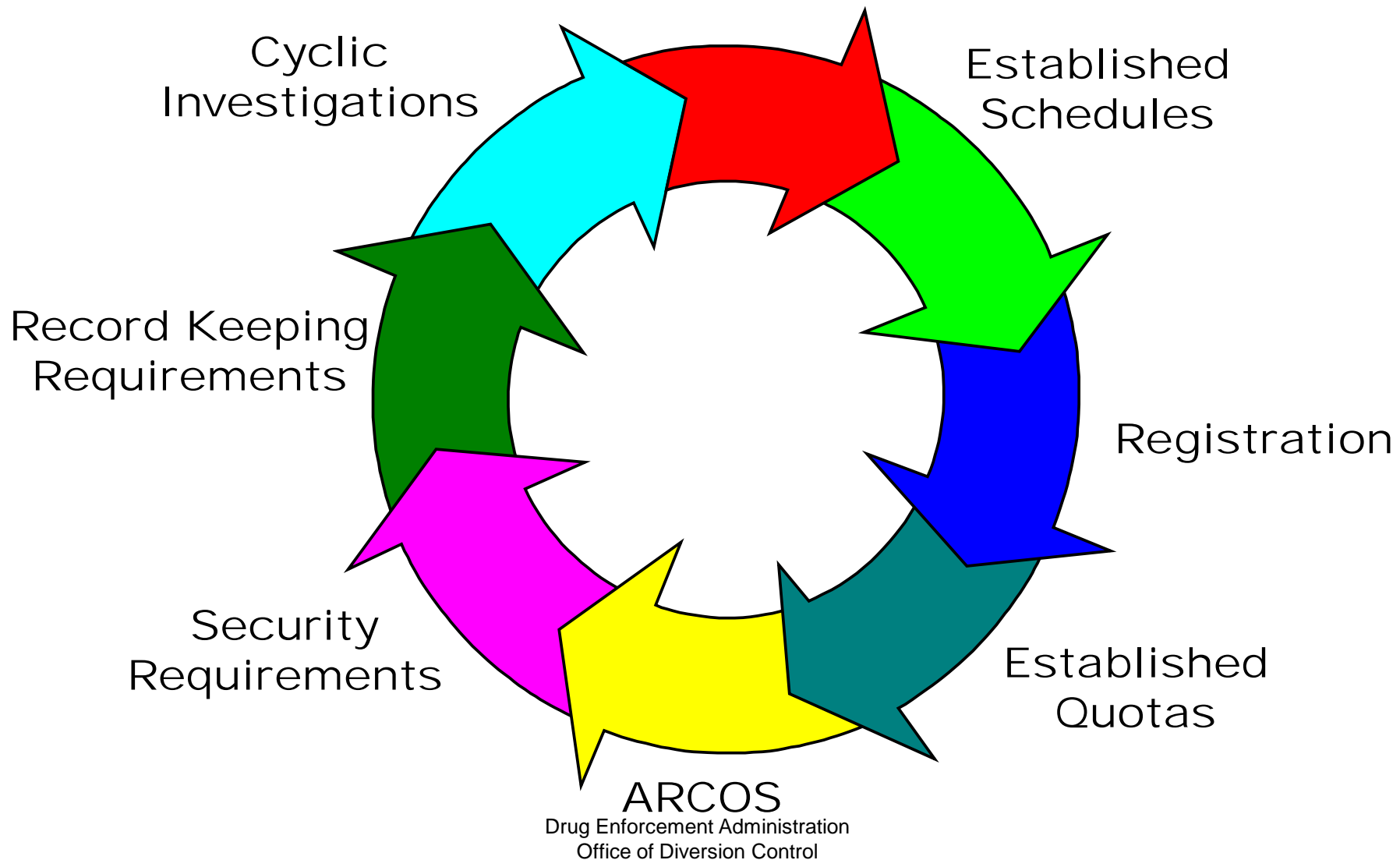


1,677,537 (1/18/2017)

- **Practitioners:** 1,253,249
- **Mid Level Practitioner:** 319,280
- **Retail Pharmacies:** 72,126
- **Hospital/Clinics:** 17,674



Closed System of Distribution





Closed System of Distribution

The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety



Drugs of Abuse





Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

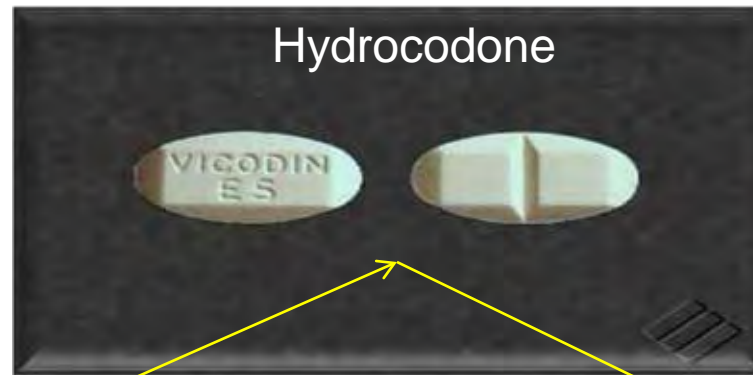
Hydrocodone

- Ø Hydrocodone / Acetaminophen (toxicity)
- Ø Similarities:
 - Structurally related to codeine
 - Equal to morphine in producing opiate-like effects
- Ø Brand Names: Vicodin[®], Lortab[®], Lorcet[®]
- Ø **October 6, 2014 moved to SCHEDULE II**
- Ø “Cocktail” or “Trinity”
 - Ø Hydrocodone
 - Ø Soma [®] / carisoprodol
 - Ø Alprazolam / Xanax[®]



Street prices: \$2 to \$10+ per tablet depending on strength & region

The Trinity



Opiate



Muscle Relaxant



Benzodiazepine

Oxycodone

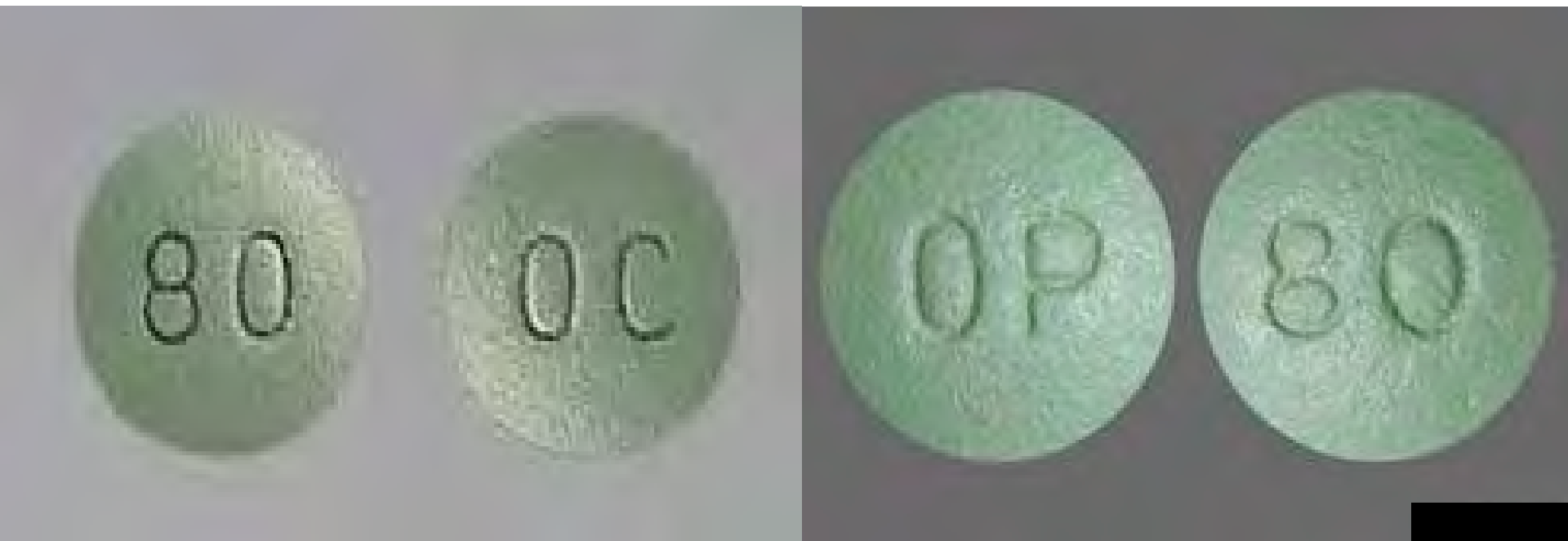
- § OxyContin controlled release formulation of Schedule II oxycodone
 - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
 - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
 - 10, 15, 20, 30, 40, 60, 80mg available

- § Effects:
 - Similar to morphine in effects and potential for abuse/dependence
 - Sold in “Cocktails” or the “Holy Trinity”
 - § Oxycodone, Soma ® / Xanax®

- § Street price: Approx. \$80 per 80mg tablet

NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.

Oxycodone HCL CR (OxyContin®) Reformulation





New OxyContin® OP



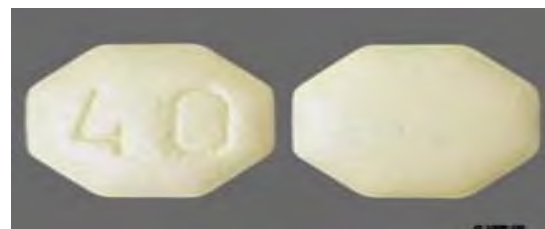
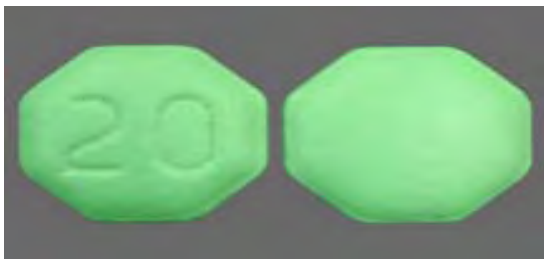
<p>08-27-2010, 01:11 AM</p> <p>mz.mary420 Member</p>  <p>Join Date: May 2010 Location: down south Posts: 6</p>	<p>#17</p> <p>well just got ours and they suck! when snorted the pill balls up in your nose and gets stuck, so i tried sucking on one and it did ok, but tastes nasty. No way you can shoot them as metioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over \$700.00 to get my 80s filled and i probably wont even get half my money back 😞</p> <p>* if anyone has tried to smoke this new formulated shit, please post! thanks</p> <p>Quote</p>
<p>08-27-2010, 06:09 AM</p> <p>mephist00 Member</p>  <p>Join Date: Apr 2008 Location: NY Age: 25 Posts: 628</p>	<p>#18</p> <p>ya my friend has tried to smoke the new ones... said its very harsh on the lungs and throat..</p> <p>so far the only way ive been able to beat the time release, is use a hose clamp to grind it very fine, and snort it.. it doesnt gel up like you would think (doesnt gel up like the football shaped generic 40's do anyways) it just kinda turns snotty.. but if you can get it down fast it seems to work ok</p> <p>Quote:</p> <p>Originally Posted by stalk <i>I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.</i></p>



Oxymorphone Extended Release Opana ER® (Schedule II)

Ø Opana ER® - (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming popular and is abused in similar fashion to oxycodone ; August 2010 (Los Angeles FD TDS)
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: \$10.00 – \$80.00



Hydromorphone



Other Opiates of Interest



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 100 mg



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 15 mg



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 30 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 30 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 100 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 60 mg



Methadone- 5mg &10mg



Methadone 40 mg



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40 mg

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Usual Dosage:
See accompanying literature for dosage.

Keep tightly closed.

Dispense in a tight container (USP) with a child-resistant closure.

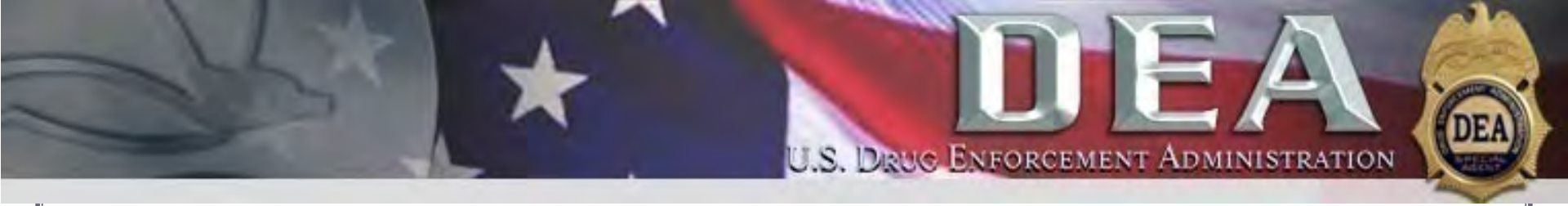
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.,
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Legal Obligations: DEA Registrant





Effective Controls

- § All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

- § In order to determine whether a registrant has provided **effective controls** against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to **prevent diversion**.

21 CFR § 1301.71(a)



Suspicious Orders

Non-practitioners of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

21 CFR § 1301.74(b)



Prescriptions

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.



21 CFR § 1306.04(a)

United States v Moore 423 US 122 (1975)



CDC Guidelines for Prescribing Opioids for Chronic Pain

§ Clinical Reminders:

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient



CDC Guidelines for Prescribing Opioids for Chronic Pain

- § Use immediate-release opioids when starting
- § Start low and go slow
- § When opioids are needed for acute pain, prescribe no more than needed
- § Do not prescribe ER/LA opioids for acute pain
- § Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed



CDC Guidelines for Prescribing Opioids for Chronic Pain

- § Evaluate risk factors for opioid-related harms
- § Check PDMP for higher dosages and prescriptions from other providers
- § Use urine drug testing to identify prescribed substances and undisclosed use
- § Avoid concurrent benzodiazepine and opioid prescribing
- § Arrange treatment for opioid use disorder if needed



Corresponding Responsibility by Pharmacist

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

21 CFR § 1306.04(a)





Corresponding Responsibility by Pharmacist

- § A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.
- § When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!





The Last Line of Defense



U.S. Drug Enforcement Administration
Office of Diversion Control



Potential Red Flags

Many customers receiving the same combination of prescriptions;
cocktail

Many customers receiving the same strength of controlled substances;
no individualized dosing: multiple prescriptions for the strongest dose

Many customers paying cash for their prescriptions

Early refills

Many customers with the same diagnosis codes written on their
prescriptions;

Individuals driving long distances to visit physicians and/or to fill
prescriptions;



Potential Red Flags continued

- C Customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and
- C Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).
- O Overwhelming proportion of prescriptions filled by pharmacy are controlled substances
- P Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctor's prescription
- V Verification of legitimacy not satisfied by a call to the doctors office



www.nabp.net



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 **QUESTION? CHAT IS AVAILABLE**

Meet the NABP Executive Committee



The 2015-2016 NABP Executive Committee, including President Edward G. McGinley, MBA, RPh, were inaugurated at the 111th Annual Meeting. [Learn More](#)


2015-2016 Executive Committee

[Officers](#)

Chairperson – [Jennifer L. Adams, RPh](#)
President – [Edward G. McGinley, MBA, RPh](#)
President-Elect – [Neil Ward, MBA, RPh](#)

Do You Know What a Doctor Shopper Looks Like?

Americans abuse prescription drugs more than cocaine, heroin, and hallucinogens combined. The "Red Flag" video helps pharmacists identify the warning signs of prescription drug abuse and diversion.



[Red Flags for Pharmacists](#)

[Verified Pharmacy Program](#)

[CPE Monitor](#)

[Safe Online Pharmacies](#)

 **NEWSROOM HEADLINES**

RELATED 



Red Flag?

What happens next?

You attempt to resolve...



Resolution is comprised of many factors

- § Verification of a valid practitioner DEA number ! It is not, **however**, the end of the pharmacist's duty. Invalid DEA number = Invalid RX
- § Resolution cannot be based solely on patient ID and prescriber verification.
- § You must use your professional judgment, training and experience...we all make mistakes
- § Knowledge and history with the patient
- § Circumstances of prescription presentation
- § Experience with the prescribing practitioner
- § It does not require a call to the practitioner for every CS RX
- § This is not an all-inclusive list...



Who do I call to report a practitioner?

- Ø State Board of Pharmacy, Medicine, Nursing, Dental
- Ø State, County, Local Police
- Ø DEA local office and Tactical Diversion Squad
- Ø Health Department
- Ø HHS OIG if Medicare, Medicaid fraud



The DEA Response





Drug Enforcement Administration

360 Degree Strategy





Community Partnerships



- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education and prevention efforts.



DEA Registrant Initiatives

Distributor Initiative

Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances

Briefings to **99** firms with **309** registrations

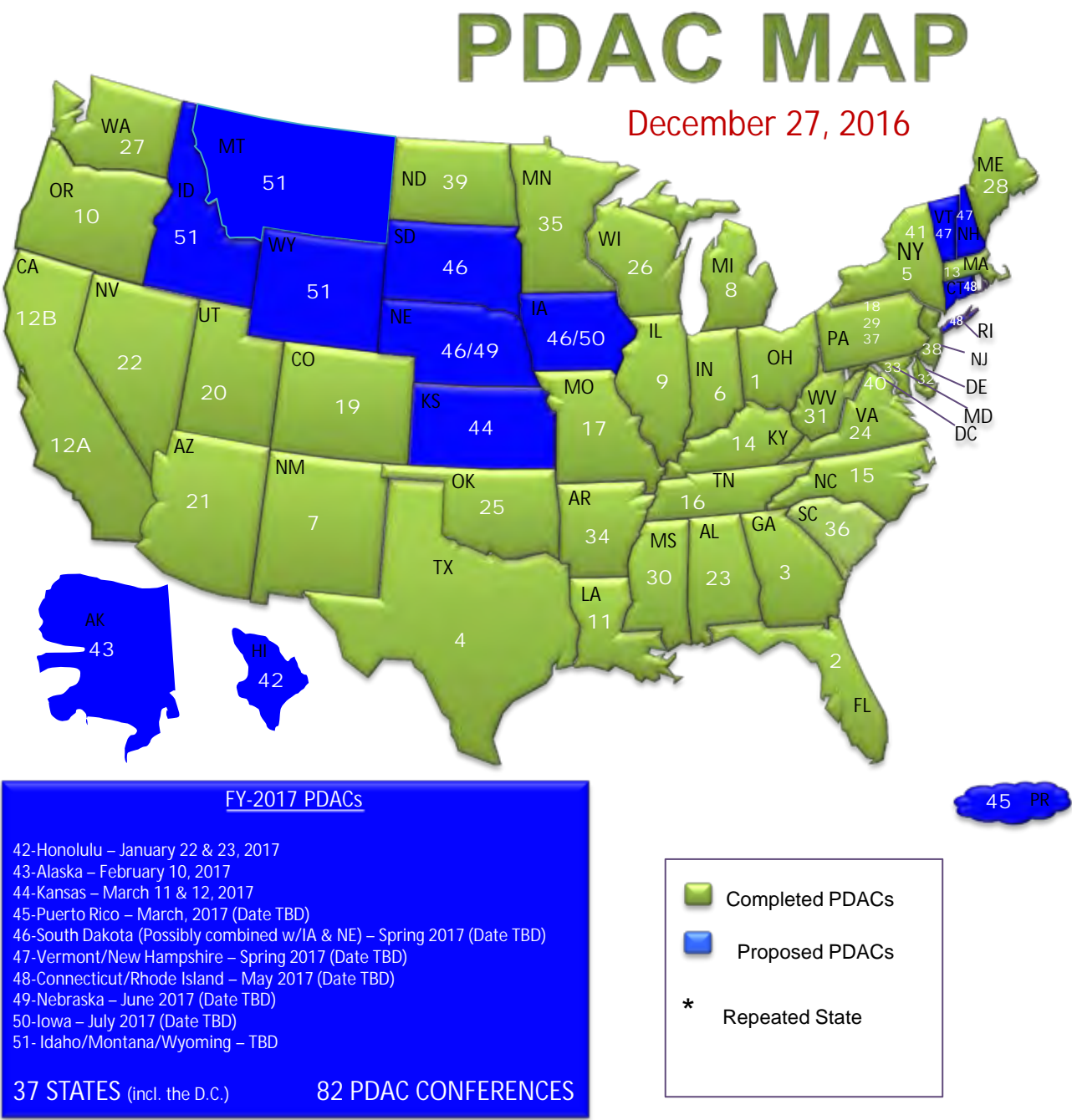


DEA Registrant Initiatives

Pharmacy Diversion Awareness Conference

This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity

Completed PDACs		Attendance
FY-2011		
1-Cincinnati, OH 9/17-18/11		75
FY-2011 Total Attendance		75
FY-2012		
2-WPB, FL 3/17-18/12		1,192
3-Atlanta, GA 6/2-3/12		328
4-Houston, TX 9/8-9/12		518
5-Long Island, NY 9/15-16/12		391
FY-2012 Total Attendance		2,429
FY-2013		
6-Indianapolis, IN 12/8-9/12		137
7-Albuquerque, NM 3/2-3/13		284
8-Detroit, MI 5/4-5/13		643
9-Chicago, IL 6/22-23/13		321
10-Portland, OR 7/13-14/13		242
11-Baton Rouge, LA 8/3-4/13		259
12A-San Diego, CA 8/16-17/13		353
12B-San Jose, CA 8/18-19/13		434
13-Boston, MA 9/21-22/13		275
FY-2013 Total Attendance		2,948
FY-2014		
14-Louisville, KY 11/16-17/13		149
15-Charlotte, NC 2/8-9/14		513
16-Knoxville, TN 3/22-23/14		246
17-St. Louis, MO 4/5-6/14		224
18-Philadelphia, PA 7/12-13/14		276
19-Denver, CO 8/2-3/14		174
20-SLC, UT 8/23-24/14		355
21-Phoenix, AZ 9/13-14/14		259
FY-2014 Total Attendance		2,196
FY-2015		
22-Las Vegas, NV 2/7-8/15		193
23-Birmingham, AL 3/28-29/15		296
24-Norfolk, VA 5/30-31/15		410
25-Oklahoma City 6/27-28/15		253
26-Milwaukee, WI 7/25-26/15		114
27-Seattle, WA 8/8-8/9/15		210
28-Portland, ME 9/12-9/13/15		94
FY-2015 Total Attendance		1,570
FY-2016		
29-Pittsburgh, PA 12/10-11/15		196
30-Jackson, MS 1/9-10/16		185
31-Charleston, WV 2/27-28/16		245
32-Wilmington, DE 3/19-20/16		111
33-Towson, MD 4/17-4/18/16		442
34-Little Rock, AR 6/11-12/16		216
35-Minneapolis/St. Paul, MN 7/8-9/16		151
36-Hilton Head, SC 8/15-16/16		157
37-Camp Hill, PA 8/27/16		84
38-New Brunswick, NJ 9/18-19/16		304
39-Fargo, ND 10/2/16		68
40-Washington, DC 11-19-20/16		414
41-Buffalo, NY 12/9-12/10/16		239
Total Attendance To Date		12,030





DEA Registrant Initiatives

- § The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public
- § DEA and FSMB are currently working on developing strategies to [work more effectively and jointly](#) on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation



DEA Registrant Initiatives

“Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances”

- § Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and “red flag” warning signs related to prescribing and dispensing controlled substance prescriptions
- § The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny
- § NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.

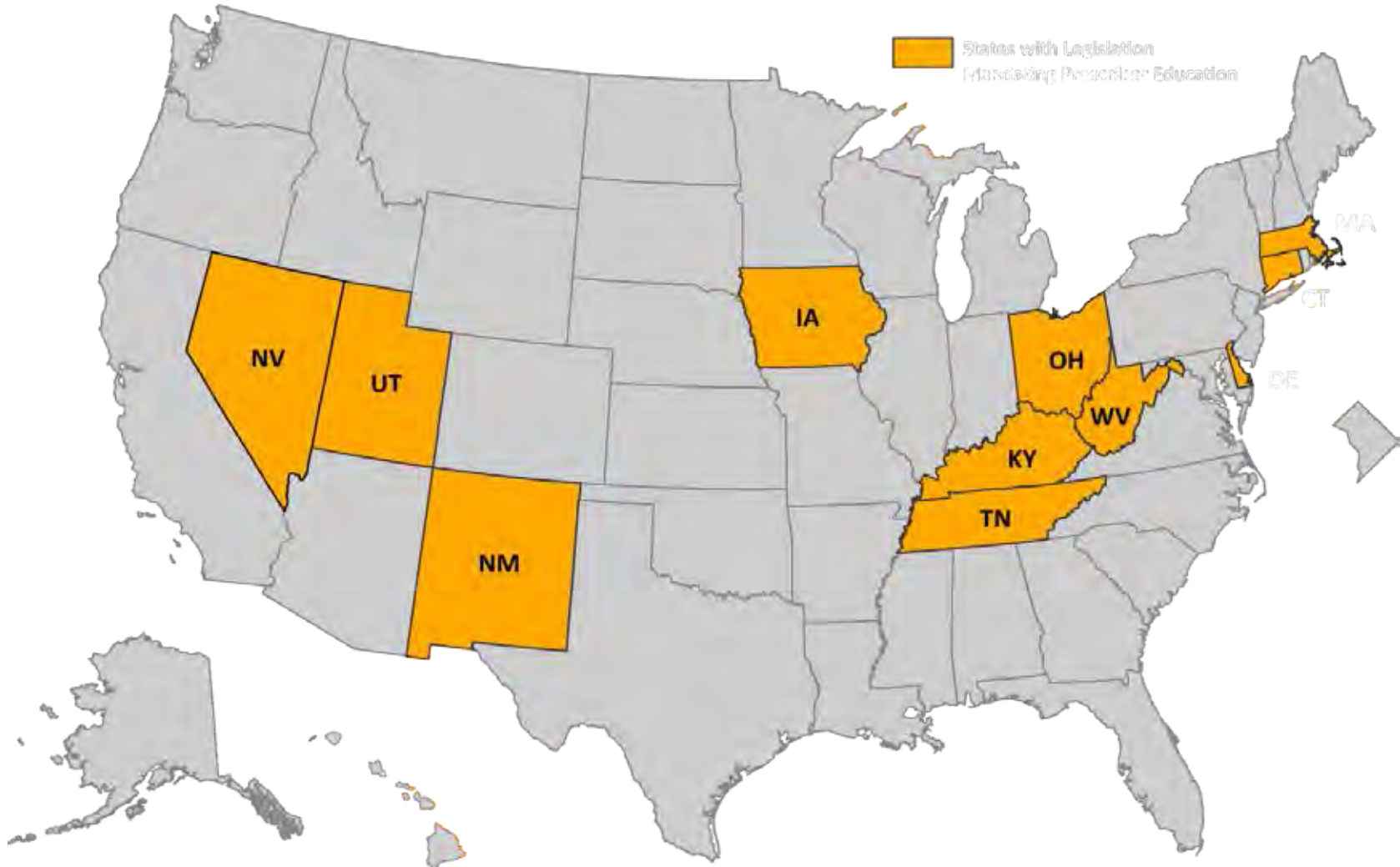


Scheduled Investigations

- § Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations
- § Increase in the frequency of the regulatory investigations
- § Verification investigations of customers and suppliers



Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education





Maine

- § Second State to Mandate Electronic Prescribing
- § Prescribers are required to undergo addiction training every 2 years
- § Set cap on daily strength for opioid prescribing:
 - Acute pain – 7 days
 - Chronic pain – 30 days
- § To begin January 2017



National Take Back Initiative

Got Drugs?

Turn in your
unused or expired
medication for safe disposal
Saturday

Click here
for a collection
site near you.

APRIL 29, 2017

dispose

unused
Rx

DEA

STATE MEDICAL BOARD

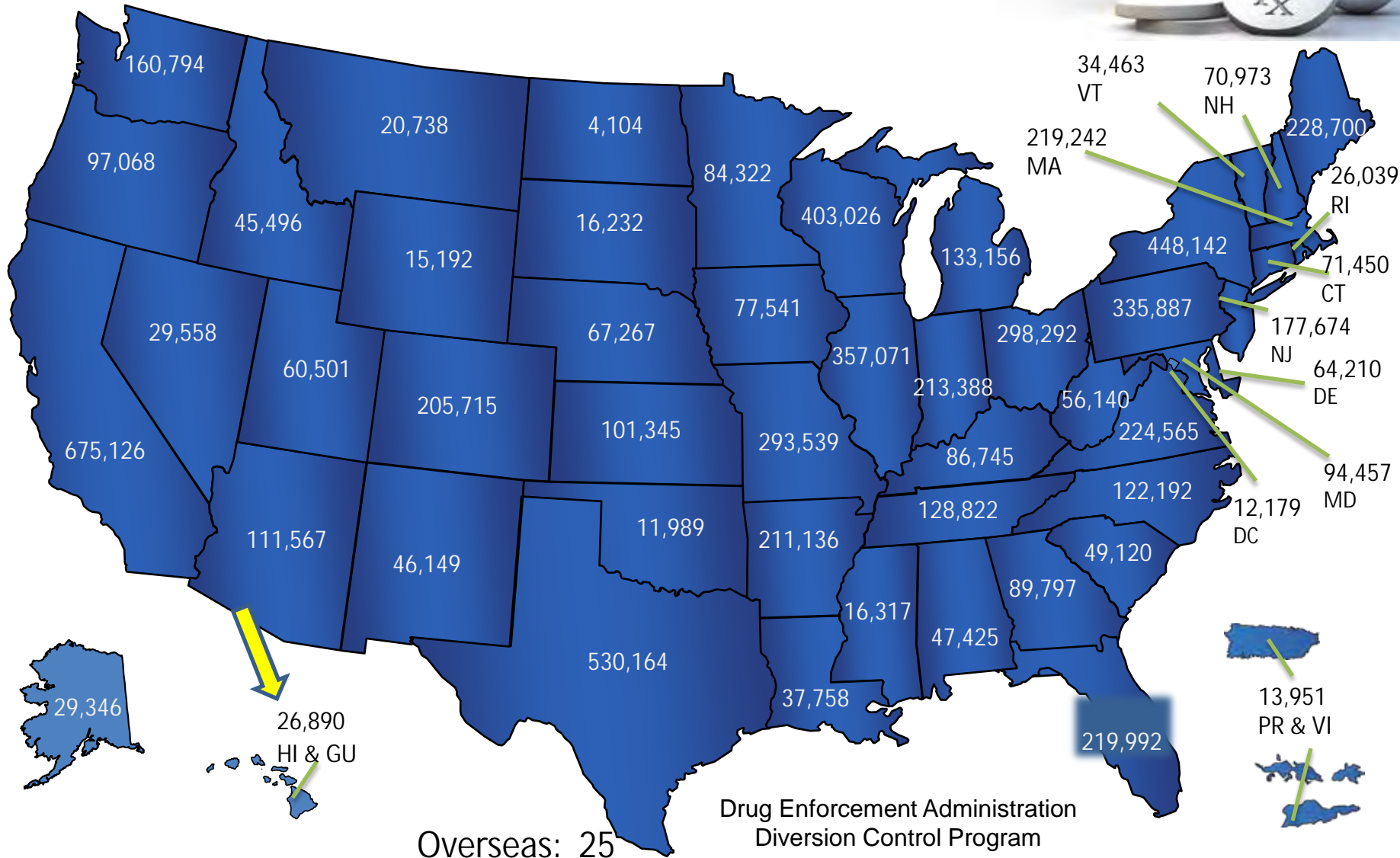
The poster features a large blue pill with the word "dispose" written on it, and a white pill with "unused" and "Rx" written on it. In the background, there is a large yellow and purple DEA seal. At the bottom, there are several logos of participating organizations, including the DEA, the U.S. Department of Justice, the U.S. Department of Health and Human Services, and the State Medical Board.

10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration
Office of Diversion Control

National Take Back I-XII Totals:

Total Weight Collected (pounds): 7,202,977 (3601 Tons)



Overseas: 25

Drug Enforcement Administration
Diversion Control Program

Secure and Responsible Drug Disposal Act of 2010





Ultimate User

Ultimate user means as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

- ü Disposal in Trash (ONDCP method); or
- ü Flushing (FDA opioids and select CSs)
- ü National Take-back Event (DEA)
- ü Transfer to Law Enforcement
- ü (Police Station Receptacles or local Take-back events)
- ü DEA





Secure and Responsible Drug Disposal Act of 2010

§ CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

21 USC § 822(f) & (g)

§ Participation is voluntary

21 USC § 822(g)(2)

§ Registrants authorized to collect:

- Ø Manufacturers
- Ø Distributors
- Ø Reverse Distributors
- Ø Narcotic Treatment Programs
- Ø Hospitals/clinics with an on-site pharmacy
- Ø Retail Pharmacies

21 CFR § 1317.40

*Authorized
collectors, as
registrants, are
readily familiar with
the security
procedures and
other requirements
to handle
controlled
substances.*



Law Enforcement

- § Law Enforcement may continue to conduct take-back events.
- § Any person may partner with Law Enforcement.
- § Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- § Authorized collection receptacles and inner liners “should” be used.

21 CFR § 1317.35 and 1317.65



Collection





Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) & (4) and 21 CFR § 1300.01(b)





Design of Collection Receptacles

- § Securely fastened to a permanent structure.
- § Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- § Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.
- § Outer container must display a sign stating only Schedule II-V and non-controlled substances are acceptable substances.
- § Schedule I controlled substances are not permitted to be collected

21 CFR § 1317.75(e)





Collection Receptacle Inner Liner

- ü Waterproof, tamper-evident, and tear-resistant.
- ü Removable and sealable upon removal without emptying or touching contents.
- ü Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- ü Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- ü Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)



Collection Receptacles

- Ø Ultimate users *shall* put the substances directly into the collection receptacle.
- Ø Controlled and non-controlled substances may be comingled.
- Ø Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Ø Registrants **shall not dispose of stock or inventory** in collection receptacles.

21 CFR § 1317.75(b) and (c)



Collection Receptacle Location

- § Registered location – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- LTCF – located in secure area regularly monitored by LTCF employees.
 - Hospital/clinic – located in an area regularly monitored by employees---not in proximity of where emergency or urgent care is provided.
 - NTP – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)



Mail-Back Program

Requirements of mail-back program

- Ø Only lawfully possessed schedules II-V controlled substances may be collected
- Ø Controlled and non-controlled substances may be collected together
- Ø **Must have method of on-site destruction**

21 CFR § 1317.70 (b)

DEA Registrant who sells mail-back packages for another registrant is **NOT** required to modify registration as a collector

Registrant Disposal





Registrant Disposal - Inventory

Practitioner & Non-Practitioner may **dispose of inventory**

- § Prompt on-site destruction
- § Prompt delivery to **reverse distributor** by common or contract carrier or **reverse distributor pick-up**
- § Return and recall : Prompt delivery by common or contract carrier or pick-up at the registered location

Practitioner may also request assistance from the SAC

Non-Practitioner may also transport by its own means

21 CFR § 1317.05(a) and (b)



DEA Form 41

- § Form 41 shall be used to record the **destruction of all controlled substances, including controlled substances acquired from collectors.**
- The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
 - Exceptions for DEA Form 41:
 - § Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
 - § Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41



Abandoned Controlled Substances

- Circumstances when there is no authorized person to dispose of controlled substances
 - Ø School
 - Ø Summer camp
 - Ø Hospital
- Return to ultimate user is not feasible
- Options
 - Ø Contact law enforcement or DEA
 - Ø Destroy on-site

Pharmaceutical Wastage





Pharmaceutical Wastage

Not subject to **21 CFR Part 1317**

- Destruction does not have to be “non-retrievable”
- DEA Form 41 must not be utilized

§ Dispensing must be recorded as a record

21 CFR § 1304.22(c)

§ Clarification memorandum on DEA website at
www.deaDiversion.usdoj.gov

Miscellaneous Pharmacy Topics





Multiple Prescriptions Schedule II Controlled Substances

- Individual practitioner may issue multiple prescriptions which authorizes patient to receive 90-day supply of C-II
 - § Each separate prescription is for legitimate medical purpose issued by practitioner acting in usual court of professional practice
 - § Written instructions on each prescription indicating earliest date it can be filled
 - § Doesn't cause undue risk of diversion by patient
 - § Compliance with all other elements of CSA and state laws



Faxed Prescription vs. EPCS

- True electronic prescriptions are transmitted as **electronic data files** to the pharmacy, whose application imports the data file into its database.
- A system that allows the prescriber to “sign” his/her name does **NOT** conform to EPCS regulations.
- A facsimile with a written signature is **NOT** an electronic Rx.

21 CFR § 1306.05(d)





Hospice & LTCF Prescriptions

Schedule II narcotic substances may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile

§ Practitioner (or agent) must note it is hospice patient

§ Facsimile serves as original written prescription

21 CFR § 1306.11(f), (g) & 1306.13(b)

Schedule III-V prescription

– Written prescription signed by a practitioner,
or

– Facsimile of a written, signed prescription



Distribution by Pharmacy to Practitioner

- Practitioner registered to dispense may distribute a quantity of such substance to another practitioner for general dispensing
 - Purchaser must be registered with DEA
 - Schedule III-V - records by purchaser and receiver must conform to 21 CFR § 1304.22(c)
 - Schedule I or II - an order form must be used and must conform to 21 CFR § 1305
 - Total number of controlled substances dispensed cannot exceed 5% of total controlled substances dispensed

21 CFR § 1307.11(a)(1)



Repackaging by Pharmacy

- Practitioner can prepare, compound, package, or label in the course of his professional practice
21 CFR § 1300.01(b)
- Pharmacy can **NOT** repackage drugs (ie 100 ct bottle packaged in smaller size bottles) and sell the drugs in the form of a distribution to any DEA Registrant – including practitioner office.
- Violation of DEA and FDA regulations

Questions?



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U.S. Drug Enforcement Administration
Office of Diversion Control